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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,490	11/23/1999	RUDOLF ECKARDT	105492-478-CON	3882
24964	7590	08/08/2005	EXAMINER	
GOODWIN PROCTER L.L.P 103 EISENHOWER PARKWAY ROSELAND, NJ 07068			MCKENZIE, THOMAS C	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/447,490	ECKARDT ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie, Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-29 is/are allowed.
- 6) ☒ Claim(s) 9,13,14 and 17-20 is/are rejected.
- 7) ☐ Claim(s) 10-12,15,16 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A

DETAILED ACTION

1. This action is in response to amendments filed on 5/17/05. Applicant has amended claims 9-13. Claims 14-29 are new. Claims 9-13 were previously rejected. There are twenty-one claims pending and twenty-one under consideration. Claims 9-29 are method of making claims. This is the fourth action on the merits. The application concerns a process of making the anti-convulsant drug Carbamazapine from iminostilbene. Carbamazapine itself was first patented in 1960.

Response to Amendment

2. Applicants' amendment to the first line of the specification overcomes the objection made in point #3 of the previous office action. Applicants have amended the specification to remove the new matter. That overcomes the objection made in point #3. Applicants have amended claim 9 to restrict the possible solvent choices to two. Those two solvent choices are aqueous acetic acid and alcoholic acetic acid. This is amply supported in the specification as filed and overcomes the indefiniteness rejections made in points #5-#8 and the written description rejections made in points #10 and #11. Alcoholic acetic acid would include all alcohol solvents and point #7 is rendered moot. Upon further reflection, Applicants' limitation, "reacting iminostilbene with an alkali cyanate in aqueous acetic acid solution" would cover both having the iminostilbene and the alkali

cyanate are dissolved in aqueous acetic acid solution and also having a aqueous acetic acid solution of an alkali cyanate added to the iminostilbene. While the claim is broad it is not indefinite. Thus, the indefiniteness rejection made in point #9 is withdrawn. Applicants have amended claim 13 so that it no longer requires a two-step process. Thus, the separate obviousness rejection of this claim over Acklin (EP 277,095), made in point #13 of the previous office action is moot. However, claim 13 is now rejected as drawn to a one-step process.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "not strongly aprotic" is indefinite. This is not defined *ipso verba* in the specification. The IUPAC Compendium of Chemical Terminology 2nd Edition (1997) defines "aprotic" as a solvent that is "non-protogenic (in a given situation)" *i.e.* a solvent that does not lose or accept protons. Not aprotic, or more conventionally "protic" means a solvent that can lose or gain protons. Water, alcohol, and acetic acid are strong protic solvents. What do Applicants mean by "not strongly aprotic"? Is this weakly aprotic? Does it

mean strongly protic? If the former, neither of Applicants' two solvents will fit the limitation. How is this aprotic ability of a solvent measured? The term "not strongly aprotic" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "not strongly protic" does not appear anywhere in the claims or specification as filed. As discussed above, its meaning is unclear but it only appeared in the most recent amendments.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 remains rejected and claims 13, 14, and 17-20 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Acklin (EP 277,095). The reference teaches a process of making the compound Carbamazapine from iminostilbene in acetic acid using sodium cyanate. The Applicant claims such a process comprising an aqueous solution of the cyanate. The reference teaches a process with 96% sulfuric acid present. The other 4% of the sulfuric acid is water. The process is shown in the reference in Example 2 in the third paragraph, page 10 of the translation of Acklin. The difference between the claims and the reference is Applicants' added limitation that the reaction is done in an aqueous solution and the presence of sulfuric acid in the reference example, not allowed by the present claims. The reference is silent as to whether the iminostilbene and/or alkali cyanate were in solution.

Claim 14 of reference as corrected by John Koytcheff on page 6 teaches, "that acetic acid is used as acidic agent, and concurrently as solvent". Thus, the reference teaches that acetic acid alone can function as the reaction medium. In lines 1-2, page 5, the reference teaches that "a mostly water- ... free organic solution" may be used for the reaction. The word "mostly" implies that small amounts of water are permitted by the reference.

The skilled organic chemist would be motivated to delete the sulfuric acid from the working example to reduce the costs of the reagents and to eliminate a disposal problem of the used sulfuric acid. The skilled organic chemist would understand that the working example contained 4% water and would vary the amount of water present as a part of routine experimentation to maximize the yields of this process, *Ex parte Rasmussen* 123 USPQ 498, *In re Aller* 105 USPQ 233.

Applicants claim 13 adds the limitation, "not strongly aprotic". As discussed above, the meaning of this is unclear, but certainly fits the water, acetic acid, and sulfuric acid mixture taught by the reference. Applicants claim 14 requires "up to about 20% by weight of water". There is no lower limitation to the amount of water required by the present claim 14. The water present in the 96% sulfuric acid in the working example of the reference and lines 1-2, page 5 of the reference certainly contain less than 20% water but they do teach that some water is present. The present claim 17 requires the sodium cyanate taught by the reference. The present claim 18 requires a temperature between 20 and 100 °C. The reference teaches a temperature of 30 °C. Thus, the present claims 17 and 18 are made obvious. The present claim 19 requires gradual addition of the cyanate. The reference teaches addition of the cyanate "in portions". This means the cyanate

was added gradually. Thus, the present claim 19 is made obvious. The present claim 20 requires solid cyanate be added. The sodium cyanate taught in the reference is normally a solid.

Applicants argue that there is no motivation to leave out the sulfuric acid taught in the reference. The motivation to reduce costs by simplifying the process and to reduce costs by eliminate the need to dispose of used sulfuric acid was discussed previously.

Allowable Subject Matter

6. Claims 10-12, 15, 16, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 22-29 are allowed.


Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date

of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

9. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.


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